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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,646	08/21/2000	Yasuko Ozaki	053466/0286	8792

22428 7590 07/28/2006

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EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,646	OZAKI ET AL.	
	Examiner	Art Unit	
	Deborah A. Davis	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,13,15 and 16* is/are pending in the application.

4a) Of the above claim(s) *10-12 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 6-9, 13 and 15-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the Office Action mailed on April 4, 2006 has been acknowledged. Currently, claims 1-4, 6-9, 13 and 15-16 are under examination. The examiner have reintroduced the art of the previous office action mailed 11-17-04 because independent claims 1 and 3 have also been interpreted to meet the limitation of "lacking 17 or less amino acid residues from the C- terminal" of SEQ ID NO:1 and "lacking 27 or less amino acid residues from the N-terminal" could also mean lacking "0" amino acids from the "C" and "N" terminal. Therefore, the art is still applicable and the examiner apologizes for the inconvenience that this may have caused.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4, 6-9, 13 and 16-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Step (c) in claims 1 and 3 recite the limitation "and another peptide or polypeptide" is vague because it is unclear if this peptide or polypeptide is separate from the fusion protein or part of it. The relationship of the peptide or polypeptide to the fusion protein and the assay method is unclear.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 3, 7-9 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al (Blood, Vol. 84, No 6 (September 15), 1994)) in view of Hirano et al (USP#5914252).

Goto et al teaches an immunoprecipitation assay that uses an anti-HM1.24 MoAb reacted with the soluble HM1.24 antigen in a sample and determining the said antigen with a molecular weight of 29 to 33 kD (p. 1922, cols. 1 and 2, 1st para). Goto et al further teaches in his assay washing and solubilizing the cells by sonication in a lyses buffer and after centrifugation, the use of normal mouse IgG and anti-mouse secondary

antibody which served as a substrate for the HM1.24 MoAb (pg. 1924, col. 2, 3rd para). In a flow cytometry assay the anti-HM1.24 antibody was labeled with fluorescent staining for detection purposes (p. 1923, col. 1, 2nd para).

Although Goto et al teaches an immunoprecipitation assay that uses an anti-HM1.24 MoAb reacted with the soluble HM1.24 antigen, Goto et al does not teach the amino acid sequence of the HM1.24 antigen protein.

However, Hirano et al teaches a novel membrane protein polypeptide with an amino acid sequence of SEQ ID No. 1 (columns 15-17, sequence listing). The protein can be produced in large quantities and monoclonal antibodies recognizing the polypeptide can be produced, making it possible to identify rheumatoid arthritis (RA) and also prepare reagents for the clinical diagnosis thereof (column 16, lines 22-42).

It would have been obvious to one of ordinary skill in the art to modify the teaching of Goto et al to include the use of this novel membrane protein taught by Hirano et al because it is useful in the detection of rheumatoid arthritis and can be produced in large quantities (column 16, lines 32-42). One would be motivated because to include this teaching of Hirano et al because rheumatoid arthritis can be a debilitating disease; early diagnosis and treatment can reduce or slow its progression.

7. Claims 2, 4, 6 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al in view of Hirano et al and further in view of Kang et al (USP# 5,656,448).

The teachings of Goto et al in view of Hirano et al is set forth above and differ from the instant invention by failing to teach the soluble HM1.24 antigen protein or the anti-HM1.24 antibody bound to a support.

Kang et al teaches immunoassay methods where the antibody or antigen is bound to a solid support, wherein said supports could be plates or beads (col. 1, paras. 1-3), and solid supports are considered well known and conventional in the immunoassay art.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have employed a solid support (beads or plates) as taught by Kang et al in the assay methods taught by Goto et al for the convenience of contacting antigen-antibody reactions in a sample, since such solid supports are considered well known and conventional in the immunoassay art.

Claim Rejections - 35 USC § 112 – is hereby maintained.

8. Claims 1-4, 6-9, 13 and 15-16 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons set forth below.

Response to Arguments

9. Applicant's arguments filed April 4, 2006 have been fully considered but they are not persuasive:

10. Applicant argument that there is support is the specification for steps (a) and (b) have been fully considered but not found to be persuasive.

In response, applicant appears to have support for a protein having an amino acid sequence modified by lacking 17 or less amino acid residues from the C-terminal, however, the examiner cannot find support for the limitation "lacking 27 or less amino acids fro the N-terminal". The examiner found support for and N-terminal deletion of the transmembrane domain, which could be 27 amino acids, but not support for the range regarding the N-terminus as recited in the instant claims. Therefore, the new matter rejection is still applicable.

Conclusion

11. No claims are allowed.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A. Davis whose telephone number is (571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Davis Deborah can be reached on (571) 272-0818. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah A. Davis
Patent Examiner
July 3, 2006

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